



Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

(Use as many sheets as necessary)

Customer No.: 026418

Application Number	10/692 055
--------------------	------------

Filing Date	October 22, 2003
-------------	------------------

First Named Inventor	Craig D. Friedman
----------------------	-------------------

Art Unit	1615
----------	------

Examiner Name

Attorney Docket Number	501438.20501
------------------------	--------------

Sheet	1	of	3
-------	---	----	---

## U. S. PATENT DOCUMENTS

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
CH ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	A	US- 4,871,542	10-3-89	Vilhardt	
	B	US- 5,061,914	10-29-91	Busch et. al.	
	C	US- 5,496,305	03-05-96	Kittrell et. al.	
	D	US- 5,525,348	06-11-96	Whitbourne et. al.	
	E	US- 5,629,008	05-13-97	Lee	
	F	US- 5,986,034	11-16-99	DiDomenico et. al.	
	G	US- 6,039,967	03-21-00	Ottoboni et. al.	
	H	US- 6,054,142	04-25-00	Li et. al.	
	I	US- 6,111,052	08-29-00	DiDomenico et. al.	
	J	US- 6,149,678	11-21-00	DiDomenico et. al.	
	K	US- 6,177,522	01-23-01	Brady et. al.	
	L	US- 6,183,461	02-06-01	Matsuura et. al.	
	M	US- 6,207,180	03-27-01	Ottoboni et. al.	
	N	US- 6,245,090	06-12-01	Gilson et. al.	
	O	US- 6,293,923	09-25-01	Yachia et. al.	
P	US- 6,313,254	11-06-01	Meijs et. al.		
Q	US- 6,398,718	06-04-02	Yachia et. al.		
R	US- 6,531,154	03-11-03	Mathiowitz et. al.		
S	US- 6,545,097	04-08-03	Pinchuk et. al.		

**FOREIGN PATENT DOCUMENTS**

[illegible]

Examiner Signature	Casey Hooper	Date Considered	2-10-2006
-----------------------	--------------	--------------------	-----------

\*EXAMINER: Initial if reference considered; whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.**

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/692,055
Filing Date	October 22, 2003
First Named Inventor	Craig D. Friedman
Art Unit	1615
Examiner Name	
Attorney Docket Number	501438.20501

Sheet 2 of 3**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
CH	T	US- 6,444,035	02-05-02	Chudzik, et. al.	
	U	US- 6,610,317	08-26-03	Straub et. al.	
	V	US- 6,617,014	09-09-03	Thomson	
	W	US- 2002/0055786	05-09-02	Atala	
	X	US- 2002/0169066	11-14-02	Cassidy et. al.	
	Y	US- 2003/0120261	06-26-03	Gellman	
	Z	US- 2003/0008015	01-09-03	Levisage et. al.	
	AA	US- 2002/0055730	05-09-02	Yachia et. al.	
	AB	US- 2002/0172717	11-21-02	Leong et. al.	
	AC	US- 2002/0018884	02-14-02	Thomson	
↓	AD	US- 60/471,518	05-15-03	Constantino et. al.	
	AE	US- 60/471,520	05-15-03	Constantino et. al.	
	AF	US- 20001/0019719	09-06-01	Offoloni	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner Signature	<i>Casey Hagopian</i>	Date Considered	<i>2-6-2006</i>
--------------------	-----------------------	-----------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/692,055		
		Filing Date	October 22, 2003		
		First Named Inventor	Craig D. Friedman		
		Art Unit	1615		
		Examiner Name			
Sheet	3	of	3	Attorney Docket Number	501438.20501

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
CH	AG	M. Fraser, et. al., "The Future of Bladder Control - Intravesical Drug Delivery, a Pinch of Pepper and Gene Therapy", Reviews in Urology, Vol. 4, no. 1 (2002) (pages 1-11)	
	AH	D. Song, et. al., "Bladder Tissue Pharmacokinetics of IntravesicalTaxol", Cancer Chemother Pharmacol (1997), 40: 285-292	
	AI	Z. Olah, et. al., "Ligand-induced Dynamic Membrane Changes and Cell Deletion Conferred by Vanilloid Receptor 1", The Journal of Biological Chemistry, Vol. 276, No. 14, (2001) pp. 11021-11030	
	AJ	A. Macha, et. al. "A Phorboid 20-Homovanillates Induce Apoptosis Through a VR1-Independent Mechanism", Chem. Biol., 2000, 7(7)	
	AK	A. Szallasi et. al., "A Vanilloid (Capsicin) Receptors and Mechanisms" Pharmacol. Rev., 1991, 51: 159	
	AL	A. Szallasi et. al., "A Resiniferatoxin-type Phorboid Vanilloids Display Capsaicin-like Selectivity at Native Vanilloid Receptors on Rat DR6 Neurons and at the Cloned Vanilloid Receptor VR1, 1999, 128(2), 428-434	

Examiner Signature	Casey Hagopian	Date Considered	2-6-2006
--------------------	----------------	-----------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.